In the Figures

Applicants submit herewith a single Replacement Sheet of drawings containing new Figure 10. As noted above, new Figure 10 embodies the figure previously set forth in the specification at page 41. No new matter is introduced through introduction of new Figure 10. Indeed, the subject matter of the new figure was included in precisely its current form in the application, as filed. Accordingly, prompt entry of new Figure 10 is respectfully requested.

REMARKS

Reconsideration of the subject application is respectfully requested.

1. Amendments to Specification/Drawings

Applicants have amended the specification and drawings so as to transfer the plot initially presented at page 41 of the specification into new Figure 10. The plot originally presented at page 43 of the specification corresponds to the plot of original Figure 9. Accordingly, the plot at page 43 has been deleted. The corresponding narrative discussions in the specification have been amended. No new matter has been introduced by way of these amendments. Prompt entry of the proposed amendments is respectfully requested.

2. Election/Restriction

Applicants note that the Restriction Requirement has been made "final" and that claims 10-15 and 22-32 have been withdrawn from consideration in the present application. Applicants have filed a pair of divisional applications directed to non-elected subject matter, and such divisional application are co-pending herewith.

3. Specification

Applicants note that the outstanding Office Action includes an objection to the specification based upon the inclusion of two (2) figures within the body of the disclosure. Applicants have amended the specification to remove such figures from the body of the disclosure, and have incorporated new Figure 10 based on one such figure. Applicants respectfully submit that the foregoing amendments obviate the outstanding objection to the specification. Reconsideration and withdrawal of such objection are respectfully requested.

4. <u>Information Disclosure Statement</u>

Applicants note that the Information Disclosure Statement filed on July 31, 2001 has not been reviewed in connection with examination of the present application to date (based on scanning difficulties). Applicants submit herewith a copy of the July 31st Information Disclosure Statement for consideration by the examiner. If copies of the cited documents are needed, the examiner is invited to contact the undersigned. Consideration of all art cited in the July 31st Information Disclosure Statement and return of initialed PTO Form-1449's with the next Patent Office communication are respectfully requested.

5. Claim Rejections –Section 102

In the outstanding Office Action, claims 1-2, 4-9 and 16-20 stand rejected under 35 USC §102(b) based on U.S. Patent No. 5,730,934 to Holbert (the "Holbert '934 patent"), U.S. Patent No. 5,843,374 to Sizer et al. (the "Sizer '374 patent"), or U.S. Patent No. 6,194,821 to Nakamura (the "Nakamura '821 patent"). Reconsideration is respectfully requested.

a. Holbert '934 Patent

The Holbert '934 patent is directed to a method/apparatus for sterilizing packaging through irradiation with an excimer ultraviolet lamp which may be integrated on a packaging machine. The excimer ultraviolet lamp emits radiation at a substantially monochromatic wavelength within the ultraviolet band of the electromagnetic spectrum. The excimer ultraviolet lamp is composed of a quartz shell containing one of the following gaseous compounds: Ar₂, Kr₂, Xe₂, ArCl, KrCl, KrF or XeCl. In a disclosed embodiment of the Holbert '934 patent, the lamp has a central aperture through which cooling fluid is permitted to flow to remove heat from the lamp. If the excimer

ultraviolet lamp is integrated on a form, fill and seal machine, the cooling fluid may additionally function as the content that is filled into a container fabricated on the form, fill and seal machine. The materials sterilized by the Holbert '934 patent are fabricated into many different containers, such as flexible pouches, stand-up pouches, parallelpiped containers and gable top cartons, and such material may be subjected to a sterilant prior to irradiation by the excimer ultraviolet lamp, e.g., hydrogen peroxide, ozone or the like.

With initial reference to applicants' independent claim 1, the Holbert '934 patent fails to teach or suggest a system for treating a complex fluid that includes, *inter alia*, (i) a non-laser light source for generating and transmitting substantially monochromatic light, (ii) a light emitting surface positioned relative to the non-laser light source for transmission of monochromatic light therethrough, (iii) a complex fluid positioned proximate to said light emitting surface, wherein the complex fluid includes at least one component that is sensitive to a change in temperature; and (iv) a cooling fluid in thermal communication with the light emitting surface, the cooling fluid being effective to prevent the complex fluid from undergoing a temperature change damaging to the sensitive component. Thus, applicants have developed and claimed a treatment system for complex fluids whereby at least one temperature-sensitive component of the complex fluid is undamaged based on the presence of a cooling fluid that is in thermal communication with the light emitting surface through which monochromatic light is transmitted.

The sterilization system of the Holbert '934 patent is directed to an altogether different application, namely sterilization of <u>packaging</u>, and the "cooling fluid" incorporated into the Holbert apparatus is provided merely to remove heat from the lamp, i.e., prevent the lamp from over-heating. The Holbert '934 patent fails to teach or suggest a

system (as claimed by applicants) in which monochromatic light is delivered to a complex fluid in a manner that prevents damage to temperature-sensitive component(s) of such complex fluid through incorporation of a "cooling fluid in thermal communication with said light emitting surface." The significant advantages associated with applicants' claimed system for treatment of complex fluids are demonstrated in the examples contained within the specification, and further demonstrated in the Declaration of Barry Ressler Pursuant to 37 CFR §1.132 ("Ressler Declaration") filed contemporaneously herewith, incorporated herein by reference, and discussed in greater detail below.

For at least the foregoing reasons, applicants respectfully submit that independent claim 1 patentably distinguishes over the Holbert '934 patent. In like measure, dependent claims 2-9 (which depend directly from independent claim 1) patentably distinguish over the Holbert '934 patent for at least the reasons noted herein with respect to independent claim 1. Accordingly, reconsideration and withdrawal of the current rejection of claims 1-9 based on the Holbert '934 patent are requested.

Turning to independent claim 16, an advantageous system for treating complex fluids is provided that includes, *inter alia*, a fluid-tight housing that includes at least one light emitting surface having a <u>light emitting surface geometry</u> and a treatment surface having a <u>treatment surface geometry</u>, such that the foregoing geometries substantially correspond. Through a correspondence of the light emitting surface geometry and the treatment surface geometry, applicant's claimed treatment system of independent claim 16 is more effective and/or efficient.

Applicants respectfully submit that the Holbert '934 patent fails to teach or suggest a treatment system for generating/delivering monochromatic light that provides a

light emitting surface geometry that substantially corresponds to the treatment surface geometry. Dependent claims 17-20 depend directly from claim 16 and patentably distinguish over the Holbert '934 patent for at least the reasons noted with respect to independent claim 16. Accordingly, reconsideration and withdrawal of the rejection of claims 16-20 based on the Holbert '934 patent are respectfully requested.

b. Sizer '374 Patent

The Sizer '374 patent is directed to highly analogous subject matter relative to the Holbert '934 patent. As with the Holbert '934 patent, the Sizer '374 patent is directed to an apparatus for sterilizing packaging through irradiation with an excimer ultraviolet lamp which may be integrated on a packaging machine. The excimer ultraviolet lamp emits radiation at a substantially monochromatic wavelength within the ultraviolet band of the electromagnetic spectrum. The excimer ultraviolet lamp is composed of a quartz shell containing a gaseous compound. As with the Holbert '934 patent, the Sizer '374 patent discloses an embodiment wherein the lamp includes a central aperture through which cooling fluid flows to remove heat from the lamp. In circumstances where the excimer ultraviolet lamp is integrated on a form, fill and seal machine, the Sizer '374 patent teaches that the cooling fluid may be the contents that is to be used in filling a container that is fabricated on the form, fill and seal machine. The materials sterilized by the present invention are fabricated into many different containers such as flexible pouches, stand-up pouches, parallelpiped containers and gable top cartons.

Applicants respectfully traverse the examiner's reliance on the Sizer '374 patent for the reasons that closely parallel those set forth above with respect to the Holbert '934 patent. Thus, with reference to applicants' independent claim 1, the Sizer '374 patent fails

to teach or suggest a system for treating a <u>complex fluid</u> that includes, *inter alia*, (i) a non-laser light source for generating and transmitting substantially monochromatic light, (ii) a light emitting surface positioned relative to the non-laser light source for transmission of monochromatic light therethrough, (iii) a complex fluid positioned proximate to said light emitting surface, wherein the complex fluid includes at least one component that is sensitive to a change in temperature; and (iv) a cooling fluid in thermal communication with the light emitting surface, the cooling fluid being effective to prevent the complex fluid from undergoing a temperature change damaging to the sensitive component. As noted above, applicants have developed and claimed a treatment system for complex fluids whereby at least one temperature-sensitive component of the complex fluid is undamaged based on the presence of a cooling fluid that is in thermal communication with the light emitting surface through which monochromatic light is transmitted.

The sterilization system of the Sizer '374 patent (like the Holbert '934 patent) is directed to an altogether different application, namely sterilization of packaging, and the "cooling fluid" incorporated into the Holbert apparatus is provided merely to remove heat from the lamp, i.e., prevent the lamp from over-heating. The Sizer '374 patent fails to teach or suggest a system (as claimed by applicants) in which monochromatic light is delivered to a complex fluid in a manner that prevents damage to temperature-sensitive component(s) of such complex fluid through incorporation of a "cooling fluid in thermal communication with said light emitting surface." The significant advantages associated with applicants' claimed system for treatment of complex fluids are demonstrated in the examples contained within the specification, and further demonstrated in the Declaration of

Barry Ressler Pursuant to 37 CFR §1.132 ("Ressler Declaration") filed contemporaneously herewith, incorporated herein by reference, and discussed in greater detail below.

For at least the foregoing reasons, applicants respectfully submit that independent claim 1 patentably distinguishes over the Sizer '374 patent. Similarly, dependent claims 2-9 (which depend directly from independent claim 1) patentably distinguish over the Sizer '374 patent for at least the reasons noted herein with respect to independent claim 1. Accordingly, reconsideration and withdrawal of the current rejection of claims 1-9 based on the Sizer '374 patent are requested.

With reference to independent claim 16, applicants claim an advantageous system for treating complex fluids that includes, *inter alia*, a fluid-tight housing that includes at least one light emitting surface having a <u>light emitting surface geometry</u> and a treatment surface having a <u>treatment surface geometry</u>, such that the foregoing geometries substantially correspond. Through a correspondence of the light emitting surface geometry and the treatment surface geometry, applicant's claimed treatment system of independent claim 16 is more effective and/or efficient.

Applicants respectfully submit that the Sizer '374 patent (like the Holbert '934 patent) fails to teach or suggest a treatment system for generating/delivering monochromatic light that provides a light emitting surface geometry that substantially corresponds to the treatment surface geometry. Dependent claims 17-20 depend directly from claim 16 and patentably distinguish over the Sizer '374 patent for at least the reasons noted with respect to independent claim 16. Accordingly, reconsideration and withdrawal of the rejection of claims 16-20 based on the Sizer '374 patent are respectfully requested.

c. Nakamura '821 Patent

The Nakamura '821 patent is directed to a decomposition apparatus that achieves decomposition through emission of a UV light from an excimer lamp. The disclosed decomposition apparatus includes an excimer lamp emitting UV light for decomposing organic compounds, such as dioxin (polychlorinated dibenzo-para-dioxin), PCB (polychlorinated biphenyl), trichloroethylene or the like, e.g., for environmentally purifying applications. The Nakamura '821 patent is devoid of any teaching with respect to the treatment of complex fluids, and with particular reference to independent claim 1, the Nakamura '821 patent fails to teach or suggest a treatment system for the treatment of complex fluids, e.g., blood and/or vaccines, that includes, inter alia, "a cooling fluid in thermal communication with the light emitting surface," such that the cooling fluid being effective to prevent the complex fluid from undergoing a temperature change damaging to the sensitive component." Indeed, based on the "decomposition" purposes associated with the Nakamura '821 patent, applicants respectfully submit that the Nakamura '821 patent essentially teaches away from a treatment system that is configured to prevent temperature damage to sensitive component(s) within a complex fluid, as disclosed and claimed by applicants. Dependent claims 2-9 patentably distinguish over the Nakamura '821 patent for at least the reasons noted with respect to independent claim 1. Accordingly, applicants respectfully submit that claims 1-9 patentably distinguish over the Nakamura '821 patent and reconsideration/withdrawal of the rejections thereof based on the Nakamura '821 patent are respectfully requested.

With reference to independent claim 16, applicants respectfully submit that the Nakamura '821 patent fails to teach or suggest a treatment system for the treatment of

complex fluids, wherein a fluid-tight housing is provided that includes, *inter alia*, at least one light emitting surface having a <u>light emitting surface geometry</u> and a treatment surface having a <u>treatment surface geometry</u>, such that the foregoing geometries substantially correspond. Dependent claims 17-20 depend directly from claim 16 and patentably distinguish over the Nakamura '821 patent for at least the reasons noted with respect to independent claim 16. Accordingly, reconsideration and withdrawal of the rejection of claims 16-20 based on the Nakamura '821 patent are respectfully requested.

6. Claim Rejections - Section 103

In the outstanding Office Action, claims 1-9 and 16-20 are rejected under 35 USC §102(b) based on U.S. Patent No. 5,730,934 to Holbert (the "Holbert '934 patent"), U.S. Patent No. 5,843,374 to Sizer et al. (the "Sizer '374 patent"), and U.S. Patent No. 6,194,821 to Nakamura (the "Nakamura '821 patent"). Reconsideration is respectfully requested.

In advancing the foregoing obviousness rejection, the examiner acknowledges that "Holbert (US 5,730,934), Sizer et al. (US 5,834,374) and Nakamura (US 6,194,821) lack complex biological fluids such as blood products or vaccines." However, the examiner takes the position that it would have been obvious to treat complex fluids such as blood products or vaccines because the Holbert/Sizer patents may be used to treat "complex food products suitable for comestibility" and therefore "one would infer that the method could be used on other complex biological compositions without destroying the valuable properties of the sample." The examiner further advances the proposition (without record support) that "[i]t is known in the photodynamic art that the radiation destroys nucleic acids and membranes but leaves blood cells and proteins intact so long as there is not heating."

Applicants respectfully disagree with the examiner's position that it would have been obvious to treat complex fluids (e.g., bloods and/or vaccines) based on the teachings of the foregoing references. More fundamentally, applicants submit that the issue is whether the references relied upon in the foregoing rejection, either alone or in combination, teach or suggest applicants' claimed treatment systems. Again, applicants submit that the examiner's position is in error, and reconsideration/withdrawal of the rejection under Section 103 is respectfully requested.

a. Cited References Fail to Teach or Suggest Applicants' Claimed Treatment Systems

Applicants respectfully submit that there the cited references, whether taken alone or in combination, fail to teach or suggest a treatment system as recited in applicants' independent claim 1 that includes, *inter alia*, "a cooling fluid in thermal communication with the light emitting surface," such that the cooling fluid is "effective to prevent the complex fluid from undergoing a temperature change damaging to the sensitive component." Indeed, the cited references effectively teach away from the claimed invention by focusing the cooling fluid on dissipating heat from the lamp – so that it doesn't overheat – rather than addressing the significant temperature-related issues that can arise in the treatment of complex fluids. Nothing in the cited references would motivate a skilled artisan to: (1) undertake to treat complex fluids (e.g., blood or vaccines) with a monochromatic light, and/or (2) direct the cooling fluid to the light emitting surface in a manner that ensures that the complex fluid does not suffer temperature-related damage. Rather, the cited references are directed to irradiation of substantially temperature-insensitive products, and therefore fail to appreciate the significance of temperature control

at the light emitting surface. Dependent claims 2-9 patentably distinguish over the cited references for at least the reasons noted with respect to independent claim 1. For at least these reasons, applicants request reconsideration and withdrawal of the outstanding obviousness rejection of claims 1-9.

To the extent the examiner seeks to maintain an obviousness rejection of independent claim 1, the examiner is requested to provide a basis for his statement as to what is purportedly known in the photodynamic art (Office Action, page 4, last paragraph). In traversing such purported prior art teaching, applicants are entitled to review the context and basis for such prior art teaching so as to rebut a combination of such teaching with other prior art references, as posited in an obviousness rejection.

Turning to independent claim 16, applicants respectfully traverse the examiner's obviousness rejection for at least the reasons noted with respect to claim 1 above. Thus, as noted with reference to independent claim 1, the cited references fail to provide a basis for treatment of complex fluids, e.g., blood and/or vaccines, as disclosed and claimed by applicants. More fundamentally, the references relied upon in the outstanding obviousness rejection (i.e., the Holbert '934 patent, the Sizer '374 patent, and the Nakamura '821 patent) fail to teach or suggest a treatment system that includes, *inter alia*, a fluid-tight housing that includes at least one light emitting surface having a light emitting surface geometry and a treatment surface having a treatment surface geometry, such that the foregoing geometries substantially correspond. In the absence of a teaching to provide such geometric correspondence, applicants respectfully submit that independent claim 16 patentably distinguishes over the three cited references, whether taken alone or in combination. Dependent claims 17-20 patentably distinguish over the cited combination

for at least the reasons noted with respect to independent claim 16. Accordingly, reconsideration and withdrawal of the outstanding obviousness rejection of claims 16-20 are earnestly solicited.

b. The Ressler Declaration - Advantageous and Unexpected Results

In addition to the deficiencies in the obviousness rejection as described herein above, applicants submit herewith a Declaration of Barry Ressler (the "Ressler Declaration") in further support of their patentability position. As set forth in the Ressler Declaration, a system for treating complex fluids was fabricated under the supervision of applicants and in accordance with the subject matter of claim 1 of the Application (referred to as the "Treatment System"). The Treatment System substantially corresponded to the treatment apparatus schematically depicted in Figs. 1-4 of the Application. The Treatment System was used in treating blood components in accordance with claims 1-9 and 16-20 of the Application, and test results were set forth in two reports appended to the Ressler Declaration:

- Exhibit A: Report entitled "T3I Evaluation of Blood Components
 Irradiated by a Novel Monochromatic Light Source" prepared by Edward L.
 Snyder, M.D. et al. at the Yale University School of Medicine, Department of Laboratory Medicine, Blood Bank Research and Development
 Laboratory (the "Yale Report") (dates redacted);
- Exhibit B: Report entitled "Evaluation of T3I Pathogen Inactivation
 System Using Porcine parvovirus" prepared by MicroBioTest, Inc., a
 company specializing in microbiology and virology laboratory procedures
 (the "MBT Report") (dates redacted).

The Ressler Declaration summarizes the test results set forth in the Yale Report and the MBT Report, and the conclusions reached by the authors of the respective studies. As set forth in the Ressler Declaration, the Yale study involved the treatment of fresh frozen plasma, platelet concentrates, red blood cells, Adsol® solution (Baxter International, Deerfield, IL), and packed red blood cells using a claimed Treatment System. The results of the tests set forth in the Yale Report were outstanding.

- "No clinically significant effect due to irradiation [was] seen on the aliquots of fresh frozen plasma irradiated [with the claimed Treatment System] and stored for 24 hours as performed under the experimental conditions used." [Ressler Declaration, ¶11; Yale Report, page 6.]
- "There is no clinically significant effect on platelets treated with high, low or medium doses of radiation [supplied by the claimed Treatment System] and then stored for up to 24 hours." [Ressler Declaration, ¶12; Yale Report, page 7.]
- "For whole blood, radiation at different intensities produced no evidence of radiation-induced damage [with the claimed Treatment System]. Rather, the damage that was seen was attributable to sampling error and time of storage."

 [Ressler Declaration, ¶13; Yale Report, page 8.]
- "For Adsol, radiation at different intensities produced no evidence of radiation-induced damage [with the claimed Treatment System]." [Ressler Declaration,
 ¶14; Yale Report, page 9.]
- "Packed red cells are not affected by T3I radiation using the protocols performed under this trial [with the claimed Treatment System]." [Ressler Declaration, ¶15; Yale Report, page 9.]

Indeed, the authors of the Yale Report left no question as to the advantageous results achieved with the claimed Treatment System for purposes of blood treatment:

While admitting that the sample population is small, under the conditions evaluated there appears to be no clinically significant damage inflicted on blood products due to T3I-induced irradiation [using the claimed Treatment System]...Thus, we believe that pending the results of more biologically intense data analyses, the T3I radiation process does not harm red blood cells, platelets or plasma proteins...Impression: T3I radiation methodology as used in this protocol, does not harm blood products used for transfusion."

Ressler Declaration, ¶16; Yale Report, page 10 (emphasis in original).

Based on the test results set forth in the Yale Report and the conclusions advanced therein, it is clear that the claimed Treatment System is effective to treat a complex fluid [i.e., fresh frozen plasma, platelet concentrates, red blood cells, Adsol® solution, and packed red blood cells] that includes "at least one component that is sensitive to a change in temperature" and that the claimed Treatment System is further "effective to prevent the complex fluid from undergoing a temperature change damaging to the sensitive component." The advantageous performance of the claimed Treatment System is neither taught nor suggested by the references relied upon in the current Office Action, and is clearly unexpected based on prior art efforts to treat complex fluids, e.g., blood samples, through irradiation.

Turning to the MBT Report, the "T3I Hemalight" system used in the MBT testing corresponded to the Treatment System referenced in the Yale testing and further corresponds to applicants' currently claimed treatment systems. [See Ressler Declaration, ¶¶ 7, 19.] The test reports in the MBT Report demonstrate that fresh frozen

plasma and platelets were effectively treated using the claimed Treatment System. The author of the MBT Report summarized MBT's highly favorable conclusions as follows:

When *Porcine parvovirus* (PPV)-spiked fresh frozen plasma (FFP) and platelet bags were exposed to T3I "Hemalight" system [the claimed Treatment System] by the sponsor, T3I "Hemalight" system inactivated $\geq 5 \log_{10}$ of infectious PPV, as compared to the process controls...These conclusions are based on observed data.

Ressler Declaration, ¶ 20; MBT Report, page 11.

As set forth in the MBT Report and explained in the Ressler Declaration, the claimed Treatment System is effective to treat a complex fluid [i.e., fresh frozen plasma and platelets] to inactivate a virus contained therein [i.e., PPV] to achieve $a \ge 5 \log_{10}$ reduction in infectious level as compared to a process control. [See Ressler Declaration, $\P21$.] Moreover, when read together, the Yale Report and the MBT Report establish that the claimed Treatment System is capable of virus inactivation [$\ge 5 \log_{10}$ reductions in infectious levels] of complex fluids that are infected, while simultaneously affecting no harm to sensitive components contained in such complex fluid. [See Ressler Declaration, $\P22$.]

As set forth in the Ressler Declaration, "the results achieved in complex fluid treatment using the claimed treatment system as described [in the Yale and MPT Reports] are highly advantageous, unexpected, and clearly neither taught nor suggested in the prior art references relied upon in rejecting applicants' pending claims, i.e., the Holbert '934 patent, the Sizer '374 patent, and/or the Nakamura '821 patent." [See Ressler Declaration, ¶23.] Stated differently, the references relied upon in rejecting applicants' pending claims, i.e., the Holbert '934 patent, the Sizer '374 patent and the Nakamura '821 patent, fail to teach or suggest a system that would be effective to treat a complex

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fluid without damage to sensitive components contained therein, as disclosed and claimed by applicants.

For the foregoing reasons, applicants respectfully submit that all pending claims are in condition for allowance. Prompt action leading to an early notice to this effect is earnestly solicited. If the examiner believes a telephone conversation with applicants' undersigned representative may assist in advancing prosecution of this application, he is invited to contact the undersigned counsel at the noted number.

Respectfully submitted,

August 23, 2004

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Attorney for Applicants

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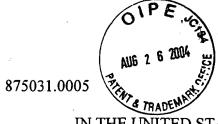
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Date of Signature



N THE UNITED STATES PATENT AND TRADEMARK OFFICE

| In re Application of: |) | |
|-----------------------------|---|-----------------------|
| John J. Coogan, Jr., et al. |) | Examiner: |
| Serial No.: 09/805,160 |) | Group Art Unit: 1625 |
| Filed: March 13, 2001 |) | Confirmation No. 9302 |

For: MONOCHROMATIC FLUID TREATMENT SYSTEMS

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Commissioner for Patents Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached form PTO-1449 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application.

The Information Disclosure Statement submitted herewith is being filed, to the best of applicants' knowledge, before the mailing date of a first Office Action on the merits.

The filing of this Information Disclosure Statement shall not be construed to be a representation that a search has been conducted, nor shall it be construed as an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

Serial No. 09/805,160

Attorney Docket: 875031.0005

It is respectfully requested that the Examiner return a copy of the attached form PTO-1449 with initials or other appropriate marks indicating consideration of the cited materials.

Respectfully submitted,

Date: July 31, 2001

Basam E. Nabulsi Reg. No. 31,645

Attorney for Applicants

CUMMINGS & LOCKWOOD Four Stamford Plaza P.O. Box 120 Stamford, CT 06904-0120 (203) 351-4321

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I hereby certify that the enclosed Information Disclosure Statement along with a PTO-1449 Form and the cited references are being deposited with the United States Postal Service as first class mail, postage prepaid, addressed to the Commissioner for Patents, Washington, D.C. 20231, on July 31, 2001.

Dated: July 31, 2001

Joan Simmons

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Applicants:

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John J. Coogan, Jr., et al.

Filing date: 3/13/01

Group Art Unit:

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U.S. PATENT DOCUMENTS

| Examiner Initial | Patent number | Date | Inventor | Class | Sub class | Filing date if appropriate |
|---------------------|---------------|----------|--------------------|-------|---------------------------------------|----------------------------|
| | 3,637,342 | 1/25/72 | Veloz | | | <u> </u> |
| | 3,987,306 | 10/19/76 | Simpson | | | |
| | 4,101,424 | 7/18/78 | Schooley et al. | | | |
| | 4,608,255 | 8/26/86 | Kahn et al. | | | |
| | 4,726,949 | 2/23/88 | Miripol et al. | | · · · · · · · · · · · · · · · · · · · | |
| | 4,837,484 | 7/6/89 | Eliasson et al. | | | |
| | 4,866,282 | 9/12/89 | Miripol et al. | | | |
| | 4,952,812 | 8/28/90 | Miripol et al. | | | |
| | 5,030,200 | 7/9/91 | Judy et al. | | | |
| | 5,150,705 | 9/29/92 | Stinson | | | |
| | 5,194,740 | 3/16/93 | Kogelschatz et al. | | | |
| | 5,232,844 | 8/3/93 | Horowitz et al. | | | |
| | 5,290,221 | 3/1/94 | Wolf, Jr. et al. | | | <u> </u> |
| | 5,433,738 | 7/18/95 | Stinson | | | |
| | 5,446,289 | 8/29/95 | Shodeen et al. | | | |

FOREIGN PATENT DOCUMENTS

| Document | Date | Country | Class | Sub | Trans | lation |
|------------|------|---------|-------|-------|-------|--------|
| number | | | | class | Yes | No |
| | | | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| | J. C. G. Doery, et al., Induction of Aggregation of Human Blood Platelets by Ultraviolet Light: Action Spectrum and Structural Changes, October 1973, Vol. 42, No. 4, pp. 551-555. |
|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | D. H. Pamphilon, et al., Applications of Ultraviolet Light in the Preparation of Platelet Concentrates, 1989, Vol. 29, No. 5, pp. 379-383. |
| | G. Andreu, et al., Ultraviolet Irradiation of Platelet Concentrates: Feasibility in Transfusion Practice, Vol. 30, No. 5, 1990, pp. 401-406. |
| | Gerard Olack, et al., Improved High-Performance Liquid Chromatographic Analysis of 8-Methoxypsoralen Monoadducts and Cross-Links in Polynucleotide, DNA, and Cellular Systems: Analysis of Split-Dose Protocols, 1993, Vol. 57, No. 6, pp. 941-949. |
| | Gasparro, et al., Research Note - The Excitation of 8-Methoxypsoralen With Visible Light: Reversed Phase HPLC Quantitation of Monoadducts and Cross-Links, 1993, Vol. 57, No. 6, pp. 1007-1010. |
| , | Schmitt, et al., New Trends in Photobiology (Invited Review) - Psoralen -Protein Photochemistry - a Forgotten Field, 1995, pp. 101-107. |
| | Blundell, et al., A Prospective, Randomized Study of the Use of Platelet Concentrates Irradiated With Ultraviolet-B Light in Patients With Hematologic Malignancy, 1996, Vol. 36, No. 4, pp. 296-302. |
| | Chin, et al., Symposium-in-Print - Virucidal Treatment of Blood Protein Products with UVC Radiation, 1997, Vol. 65, No. 3, pp. 432-435. |

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Date Considered:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP §609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

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U.S. PATENT DOCUMENTS

| Examiner Initial | Patent number | Date | Inventor | Class | Sub class | Filing date if appropriate |
|------------------|---------------|----------|-----------------------|-------|--------------|----------------------------|
| | 5,597,722 | 1/28/97 | Chapman et al. | | | |
| | 5,626,768 | 5/6/97 | Ressler et al. | | ļ | |
| | 5,654,443 | 8/5/97 | Wollowitz et al. | | | |
| | 5,702,432 | 12/30/97 | Chen et al. | | | |
| | 5,709,991 | 1/20/98 | Lin et al. | | | |
| | 5,762,867 | 6/9/98 | D'Silva | | | |
| | 5,789,150 | 8/4/98 | Margolis-Nunno et al. | | | |
| | 5,798,238 | 8/25/98 | Goodrich, Jr. et al. | | | |
| | 5,834,784 | 10/10/98 | Morgan et al. | | | |
| | 5,922,278 | 7/13/99 | Chapman et al. | | | |
| | 5,951,509 | 9/14/99 | Morris | | | |
| | 5,955,840 | 9/21/99 | Arnold et al. | | | |

FOREIGN PATENT DOCUMENTS

| | Document | Date | Country | Class | Sub | Trans | slation |
|---|----------|------|---------|-------|-------|-------|---------|
| | number | | | | class | Yes | No |
| L | | | | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| Preuss, et al., Comparison of Two Different Methods for Inactivation of Virusese in Serum, Sept. 1977, Clinical and Diagnostic Laboratory Immunology, Vol. 4, No. 5, pp. 504-508. |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The New England Jornal of Medicine, Leukocyte Reduction and Ultraviolet B Irradiation of Platelets to Prevent Alloimmunization and Refractoriness to Platelet Transfusions, December 25, 1997, Vol. 337, No. 26, pp. 1861-1869. |
| Corash, Inactivation of Viruses, Bacteria, Protozoa, and Leukocytes in Platelet Concentrates: Current Research Perspectives, Copyright © 1999, Transfusion Medicine Reviews, Vol. 13, No. 1, pp. 18-30. |
| MacDonald, et al., Infrequent Detection of TT Virus Infection in Intravenous Drug Users, Prostitutes, and Homosexual Men, March 1999, The Journal of Infectious Diseases, pp. 686-689. |
| M.L.U. del Rosario, et al., Prevention of Graft-Versus-Host Disease by Induction of Immune Tolerance With Ultraviolet B-Irradiated Leukocytes in H-2 Disparate Bone Marrow Donor, May 15, 1999, Blood, Vol. 93, No. 10, pp. 3558-3564. |
| Goodrich, The Use of Riboflavin for the Inactivation of Pathogens in Blood Products, 2000, Vox Sanguinis, Vol. 78, Supp. 2, pp. 211-215. |
| Prince, et al., Strategies for Evaluation of Enveloped Virus Inactivation in Red Cell Concentrates Using Hypericin, 2000, Photochemistry and Photobiology, Vol. 72, No. 2, pp. 188-195. |
| Azuma, et al. Comparision of Sensitivity to Ultraviolet B Irradiation Between Human Lymphocytes and Hematopoietic Stem Cells, October 1, 2000, Blood, Vol. 96, No. 7, pp. 2632-2634. |

| Examiner: | Date Considered: |
|-----------------------------------------------------------------|------------------------------------------------------------|
| | |
| EXAMINER: Initial if citation considered, whether or not citati | |
| citation if not in conformance and not considered. Include co | ppy of this form with next communication to the applicant. |

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| | | | U.S. PATE | ENT DOCUMENTS | | | | | |
| Examiner | Patent number | Date | | Inventor | Class | Sub | Filing d | date | |
| Initial | | | | | | class | if appro | | |
| | 6,113,566 | 9/5/2000 | Schiech | her | | | | T . | |
| | 6,171,549 B1 | 1/9/2001 | Kent | | | | | 1 | |
| | 6,171,777 B1 | 1/9/2001 | Cook et | t al. | | | | | |
| | 6,190,608 B1 | 2/20/2001 | Laub et | · | | | 1 | | |
| | 6,190,609 B1 | 2/20/2001 | | nan et al. | | | | | |
| | 6,194,821 B1 | 2/27/2001 | Nakamı | | | | | | |
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| <u> </u> | OTHER | R DOCUMENTS | (Including / | Author, Title, Date, Perl | tinent Pag | es, Etc.) | | | |
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